Atty Dkt. No: IDD-5657 CIP2

BBL No.: 113957-235

Figure 7 shows Carbamazepine microparticulate after homogenization (Avestin C-50);

Figure 8 is a diagram of illustrating the Microprecipitation Process for Prednisolone;

Figure 9 is a photomicrograph of prednisolone suspension before homogenization;

- 3 -

Figure 10 is a photomicrograph of prednisolone suspension after homogenization;

Figure 11 illustrates a comparison of size distributions of nanosuspensions (this invention) and commercial fat emulsion;

Figure 12 shows the X-ray powder diffraction patterns for raw material itraconazole (top) and SMP-2-PRE (bottom). The raw material pattern has been shifted upward for clarity;

Figure 13a shows the DSC trace for raw material itraconazole;

Figure 13b shows the DSC trace for SMP-2-PRE;

Figure 14 illustrates the DSC trace for SMP-2-PRE showing the melt of the less stable polymorph upon heating to 160°C, a recrystallization event upon cooling, and the subsequent melting of the more stable polymorph upon reheating to 180°C;

Figure 15 illustrates a comparison of SMP-2-PRE samples after homogenization. Solid line = sample seeded with raw material itraconazole. Dashed line = unseeded sample. The solid line has been shifted by 1 W/g for clarity;

Figure 16 illustrates the effect of seeding during precipitation. Dashed line = unseeded sample, solid line = sample seeded with raw material itraconazole. The unseeded trace (dashed line) has been shifted upward by 1.5 W/g for clarity; and

Figure 17 illustrates the effect of seeding the drug concentrate through aging. Top x-ray diffraction pattern is for crystals prepared from fresh drug concentrate, and is consistent with the stable polymorph (see Figure 12, top). Bottom pattern is for crystals prepared from aged (seeded) drug concentrate, and is consistent with the metastable polymorph (see Figure 12, bottom). The top pattern has been shifted upward for clarity. --

Page 6, line 21, "presuspension" has been changed to - - pre-suspension--;

Page 6, line 27, "presuspension" has been changed to - - pre-suspension--;

Page 6, line 31, "presuspension" has been changed to - - pre-suspension--.

Atty Dkt. No: IDD-5657 CIP2

BBL No.: 113957-235

Page 7, lines 30-31, "diagrammatically below" has been changed to - - in Figures 1 and 2 respectively--.

Page 8, line 1, "Figure 1: Method A:" has been deleted, as well as the associated figure 1;

Page 8, "Figure 2: Method B:" has been deleted, as well as the associated figure 2.

Page 11, line 18, "U.S." has been changed to -- United States--;

Page 11, line 28, "cationine" has been changed to - -cationic--.

Page 14, line 17, "presuspension" has been changed to - - pre-suspension--;

Page 14, lines 26-27, "presuspension" has been changed to - - pre-suspension--;

Page 14, line 31, "presuspension" has been changed to - - pre-suspension--.

Page 15, lines 5-6, "presuspension" has been changed to - - pre-suspension--;

Page 15, line 14, "presuspension" has been changed to - - pre-suspension--.

Page 16, line 2, "presuspension" has been changed to - - pre-suspension--;

Page 16, line 18, "presuspension" has been changed to - - pre-suspension--;

Page 16, line 27, "presuspension" has been changed to - - pre-suspension--;

Page 16, line 28, "presuspension" has been changed to - - pre-suspension--;

Page 16, line 31, "presuspension" has been changed to - - pre-suspension--.

Page 18, line 15, "Figure 3: Amorphous particles prior to homogenization (Example 1)." has been deleted, as well as the associated figure.

Page 18, "Figure 4: Particles after annealing by homogenization." has been deleted, as well as the associated figure on the top of page 19.

Atty Dkt. No: IDD-5657 CIP2

- 5 -BBL No.: 113957-235

Page 22, line 16, a period was added at the end of the sentence.

Page 23, lines 17-18, "Figure 5: X-Ray diffractogram of microprecipitated itraconazole with polyethylene glycol-660 12-hydroxystearate before and after homogenization (Example 5)." and the associated figure has been deleted.

Page 24, line 10, "2.44 um" has been changed to - - 2.44μ m--.

Page 26, line 3, "Figure 6: Carbamazepine crystals before homogenization (Example 6)." and the associated figure have been deleted.

Page 26, line 5, "Figure 7: Carbamazepine microparticulate after homozenization (Avestin C-50)" and the associated figure have been deleted;

Page 26, line 6, "(Example 6)." has been deleted.

Page 28, line 19, "Figure 8: Diagram of Microprecipitation Process for Prednisolone (Examples 9-12)" has been deleted, as well as the associated figure;

Page 29, lines 4-5, "Figure 9: Photomicrograph of prednisolone suspension before homogenization (Hoffman Modulation Contrast, 1250X magnification)" has been deleted, as well as the associated figure.

Page 29, lines 6-7, "Figure 10: Photomicrograph of prednisolone suspension after homogenization (Hoffman Modulation Contrast, 1250X magnification). has been deleted, as well as the associated figure on page 30.

Page 33, lines 16-17, "Figure 11: Comparison of size distributions of nanosuspensions (this invention) and commercial fat emulsion. (Example 13)" has been deleted, as well as the associated figure.

Page 38, Figure 12, and associated text has been deleted.

Page 39, 40, and 41 (i.e., Figures 13a, 13b, 14, 15, 16, and associated text) have been deleted in entirety.